Department: **UAMS Human Research Advisory Committee**
Policy Number: **12.3**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: Food and Drug Administration Monitoring or Audits

The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the HRAC that reviewed the investigation refuses to allow an inspection (21CFR56.115; 45CFR).

On the basis of the HRAC's or the institution's response FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the HRAC or the parent institution takes appropriate corrective action, the Agency may:

1. Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the HRAC
2. Direct that no new subjects be added to ongoing studies subject to this part
3. Terminate ongoing studies subject to this part when doing so would not subjects or
4. When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the HRAC

The parent institution is presumed to be responsible for the operation of an HRAC, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the HRAC or to a component of the parent institution determined to be responsible for formal designation of the HRAC (21CFR56.115; 45CFR).

FDA's Disqualification the HRAC or an institution. Whenever the HRAC or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the Agency under 21CFR56.120(a); 45CFR), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the HRAC or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in part 16.

The Commissioner may disqualify an HRAC or the parent if the Commissioner determines that:

The HRAC has refused or repeatedly failed to comply with any of the regulations set forth in this part, and;

The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the HRAC. The Food and Drug Administration will send notice of the disqualification to the HRAC and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the Agency may elect to publish a notice of its action in the Federal Register.

The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified HRAC or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified HRAC as conducted at a disqualified institution unless the HRAC or the parent institution is reinstated as provided in 21 CFR56.123; 45 CFR)..

Public disclosure of information regarding revocation. A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20.

Reinstatement of an HRAC or an institution. An HRAC or an institution may be reinstated if the Commissioner determines upon an evaluation of a written submission from the HRAC or institution that explains the corrective action that the institution or HRAC plans to take, that the HRAC or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under 21CFR56.121(c); 45CFR).

Actions alternative or additional to disqualification. Disqualification of an HRAC or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The Agency may also refer pertinent matters to another Federal State, or local government Agency for any action that Agency determines to be appropriate.